EXHIBIT A

Report of Samsun Lampotang, Ph.D.
In re Bair Hugger Forced Air Warming Products Liability Litigation, MDL No. 15-2666-JNE-FLN

Background and Experience

I am a Professor of Anesthesiology and an Affiliate Professor of Biomedical Engineering at the University of Florida (UF) and the founding Director of the UF Center for Safety, Simulation & Advanced Learning Technologies. I earned a PhD in Mechanical Engineering from the University of Florida in 1992, with a concentration in thermal sciences (heat transfer: conduction, convection and radiation, fluid mechanics, thermodynamics, mathematics). When studying heat transfer during my graduate studies, conduction, convection and radiation were considered as three separate and different heat transfer mechanisms with separate courses offered for each of these three distinct heat transfer processes. The specialized textbooks recommended for each of the specific courses guide engineering students in understanding the fundamentally different governing equations that describe these three inherently different processes of heat transfer.

The overarching goal of my research is patient safety that I address through (a) better hands-on clinician training through simulation and (b) making existing devices better. For my doctoral dissertation, I designed, built and evaluated an electronically-controlled anesthesia machine. I have worked on a daily basis in an anesthesia environment for 35 years. I teach UF anesthesia residents (since 1992) and practicing anesthesiologists how to safely use anesthesia machines at invited international lectures and since 2007 during hands-on anesthesia machine workshops at the American Society of Anesthesiologists (ASA) annual meeting. As part of a week-long anesthesia course to executives and engineers of anesthesia corporations/entities, I have taught FDA engineers using simulators I have designed and invented. I accepted the ASA president's invitation to serve another three-year term on the Equipment & Facilities Committee, and am on the Committees on Technology and the Committee on Education & Training of the Anesthesia Patient Safety Foundation. I am a member of the Advisory Group of the World Federation of Societies of Anaesthesiologists (WFSA) and of the Anesthesiology Performance Improvement Committee (APIC) of the University of Florida, Department of Anesthesiology. I am also an invited member of the ASA *ad hoc* committee for Advanced Technology and Training Planning Committee designing the course "Safe and Effective Use of Anesthesia Machines". I designed two of eight sections: "Pre-use check" and "Troubleshooting." I obtained formal training as a simulation instructor at the Harvard Center for Medical Simulation and teach a day-long simulation-based course to practicing anesthesiologists (8-10 per course) needing Part IV of the American Board of Anesthesiology (ABA) Maintenance of Certification in Anesthesiology (MOCA).

My work as a researcher and engineer based in a clinical department is at the intersection of anesthesia and engineering: it includes infection prevention (skin prepping, prophylactic antibiotic dosing and timing, EVD catheter tunneling training materials; urine drainage systems), temperature management (co-inventor on microwave blood/fluid warmer patent to help maintain normothermia; co-inventor on cooling football pads patent that has been

commercialized for heat stroke prevention; Peltier heat exchanger for use during anesthesia; a novel closed circuit anesthesia machine that preserves heat and humidity) and study design (including clinical studies). I have obtained grants a) from the manufacturer to design and build a skin prepping screen-based simulator for the ChloraPrep applicator that is used to train clinicians, b) from the manufacturer to study heat and moisture exchanger performance, c) from the National Football League to study the efficacy of temperature management via air-cooled football pads, and d) to evaluate the usability (simulator-based study) of working models of anesthesia equipment from multinationals prior to FDA approval. Other screen-based simulators I have designed include a screen-based simulation of the pharmacokinetics and pharmacodynamics of cefazolin (Ancef), an antibiotic that is administered prophylactically (to prevent SSI) before surgical incision and is subsequently re-dosed during prolonged surgery. We include the timing and dose of prophylactic cefazolin administration in our MOCA sessions because we have noted some confusion about proper dose and timing, among anesthesiologists who administer the cefazolin when we discuss the topic during our MOCA sessions. I am a co-investigator on a submitted translational proposal to train patients to ask clinicians to wash their hands to prevent hospital-acquired infection as recommended by the Centers for Disease Control and Prevention (CDC) and evaluate the effect of the training on behavior and patient outcomes.

I am a designer and inventor of multiple anesthesia-related products including: (a) the Hamilton Max commercial transport ventilator which emphasized usability, (b) a multi-vented urinary drainage system to reduce catheter-associated urinary tract infection, recently licensed by the University of Florida to industry, (c) the CAE/METI Human Patient Simulator, a commercial mannequin simulator analogous to a flight simulator for patients, (d) the Virtual Anesthesia Machine online simulation portfolio and web site (44,000 registered users worldwide, in 23 languages and 6 medical gas color codes), (e) a mobile device-based simulation for learning skin disinfection with the ChloraPrep, a chlorhexidine-based applicator, (f) an industry-funded panoramic simulation to learn and practice neuromuscular blockade administration, monitoring, and reversal and (g) five DoD-funded simulators for military medical personnel and reservists to practice procedural skills and aseptic techniques while deployed in austere environments. I am a named co-inventor on 40 issued US patents; one of the latest ("Materials and methods for maintaining proper body temperature") is used by high school, college and NFL football teams as well as in other sports. The full description of my body of work is in my CV, hereby incorporated into this report as Exhibit A.

I was the principal investigator on a research grant awarded to our simulation lab by CareFusion, the manufacturer of the ChloraPrep (2% chlorhexidine glugonate, 70% isopropyl alcohol) skin preparation applicator, to design and build the simulator mentioned in (e) above. We designed a screen-based simulator to explicitly address specific learning objectives that must be mastered to properly use the applicator to its full capability and to provide an engaging means for users to unlearn deeply ingrained skin prep techniques that they may have been using for decades. Among the numerous learning objectives we imbedded in the simulator, one is to use a "to and fro" pattern instead of the traditional expanding spiral pattern to obtain better application of the disinfectant. Another learning objective is to scrub for at least 30

seconds with the applicator to exfoliate dead skin cells and reach any colony forming units (CFUs) beneath them. The "to and fro" motion is illustrated at https://www.youtube.com/watch?v=UAiTfPiHYXc. *Note that the CareFusion ChloraPrep video shows one organism remaining at the end of proper skin prepping during incision.*
As part of my 35 years of research, teaching, and work in the anesthesia environment, I am very familiar with patient temperature management devices, including forced air warming devices such as the Bair Hugger. The University of Florida Academic Health Center uses the Bair Hugger device.

I was asked by Blackwell Burke P.A. to review expert reports, depositions and other materials concerning the use of forced air warming devices such as the Bair Hugger during surgery and any associated risks of surgical site infections (SSI). I am compensated at a rate of $500 per hour for my time in reviewing materials and preparing this report, $500 per hour for deposition testimony, and $500 per hour for court testimony.

In the past four years, I have provided court and/or deposition testimony for the following cases:

Becky S. Anderson v. Medtronic, Inc. et al., Washington Superior Court, County of King, No. 12-2-17928-0 SEA.

Ramirez v. Rush Copley Medical Center, In the Circuit Court of Cook County, Illinois County Department, Law Division No. 09 L 13262(D)

Materials Reviewed

In drafting this report, I have considered the materials referenced in Exhibit B.

I may use all or parts of the materials referenced herein, or summaries and depictions thereof, as exhibits or demonstrative aids to summarize or support my opinions.

Opinions

1. **The Bair Hugger Warming Unit is a Safe and Efficacious Medical Device**

The Bair Hugger is a forced air warming device; it is a reasonable, safe, easy to use and efficacious device. I disagree with Plaintiffs' assertion that the design and labeling of the Bair Hugger are defective. The Bair Hugger (BH) has a proven track record of keeping a multitude of patients warm intraoperatively and is within industry standards. The Bair Hugger design is appropriate and reasonable for the intended purpose of the Bair Hugger.

The known benefits of normothermia such as a reduction in incidence of post-operative infection and adverse myocardial events and decrease in length of stay at the hospital are well-

established and, in fact, recommended and required. Recently (May 2017), the Centers for Disease Control and Prevention (CDC) issued updated guidelines in JAMA that reaffirmed the importance of maintaining intraoperative normothermia, a function that the widely-used Bair Hugger accomplishes well. The Surgical Care Improvement Project (SCIP) metric SCIP-Inf-10 is sponsored by the Centers for Medicare and Medicaid Services – CMS, in collaboration with other national entities such as the Centers for Disease Control and Prevention and the Institute for Healthcare Improvement. It is another example of the recommendations for intraoperative normothermia. A metric of SCIP-Inf-10 is at least one temperature reading 36°C or higher within 30 minutes before or 15 minutes immediately after anesthesia end time. For short time duration anesthesia cases, the rate of warming or rewarming of patients is an important performance indicator for an active warming device because the time window to achieve the temperature target is shrunk.

By this metric, the Bair Hugger has been shown to safely maintain normothermia more effectively than alternative modalities. As an example, the Bair Hugger was demonstrated to provide twice the rate of patient temperature increase compared to the Hot Dog conductive device[i], a consideration that is important for short duration anesthesia cases. Other warming modalities may have risks not present in forced-air warming.

2. Arizant and 3M Acted Reasonably in Designing, Developing, and Marketing the Bair Hugger

I have reviewed the design and development history file as well as the 510(k) file for the Bair Hugger Models 505, 750, and 775, as well as other documents related to the design and testing of the Bair Hugger. In my opinion, Arizant/3M, and their employees and agents, acted reasonably, prudently, and within industry standards in the design, testing, evaluation and development of the Bair Hugger.

The design, testing, and risk management documents for the Bair Hugger indicate reasonable and prudent care in the development of a safe and efficacious device and incorporation of appropriate risk mitigation measures to identified risks. For example, the Model 750 510(k) submission considers the possible safety concern of airborne contamination and includes appropriate mitigations.

I have reviewed tests of the Bair Hugger filter media that indicate that it meets MERV 14 at a flowrate of 48 cfm in accordance to ASHRAE Standard 52.2-2012 and Addenda a, b, and d to Standard 201, 2015 Supplement. The filter media for the Bair Hugger models have the same Minimum Efficiency Reporting Value (MERV) 14 rating that is acceptable for general surgery.

The Bair Hugger's warnings and labeling are adequate, easily understood, and provide instructions for taping the Bair Hugger blanket to the patient. An adhesive strip at the edge of the Bair Hugger warming blanket is used to tape the blanket to the patient and prevent air from being directed to the surgical site. The warnings and labeling reasonably do not include a warning regarding a risk of infection, because there is no valid evidence of such an alleged risk

(as discussed below). In addition to the tape strip, the sterile drapes that are hung between IV poles near the patient's head form a barrier to air flow towards the surgical wound.

Arizant/3M's decision to consider but not implement potential design changes, such as the addition of a hose end filter, was reasonable, as such changes would have altered the usability (noise level, form factor) and efficacy (reduction of the flowrate of warmed gas delivered to the blanket resulting in reduced efficacy in establishing and maintaining normothermia) of the device, and were unnecessary given the lack of evidence that the Bair Hugger causes infections. It was also reasonable to not incorporate a HEPA filter for the same reasons: reduced normothermia efficacy because the higher pressure drop across a HEPA filter reduces air flow rate out of the blanket which in turn reduces convective heat transfer.

It is my opinion that Arizant/3M took the high road and acted with poise and restraint in its official response to allegations about its forced air warming technology, sticking to the science and the facts, and undertaking additional testing of the Bair Hugger. I am not aware of any misrepresentations of the safety of the Bair Hugger or forced air warming by Arizant/3M or any of its employees.

In my opinion, Arizant/3M acted transparently and appropriately in sponsoring outside independent research related to forced air warming. As an academic researcher and a recipient of industry-sponsored research that has been disseminated as a peer-reviewed publication, I personally know first-hand that academic institutions have long had safeguards and rules to ensure that industry-sponsored research is truly independent, irrespective of the results of the sponsored research and that funding from industry does not exert undue influence on the outcomes of the study. There are also strict disclosure rules, especially in medicine, that require disclosure of any potential Conflict of Interest by the authors.

3. The Bair Hugger Does Not Contaminate the Surgical Field

There is no evidence that the Bair Hugger, including its filter, is inadequate, defective, or causes infections. In one study, samples of air exiting Bair Hugger blankets did not culture any organisms.[ii] Bernards et al[iii] were able to identify during an actual infection outbreak Acinetobacter baumannii (AB), the infectious organism, in the Bair Hugger filter, indicating that the Bair Hugger filter effectively trapped AB during an actual clinical outbreak in real world conditions, with real patients, personnel and machines in actual patient care areas, and importantly not in studies using surrogates like bubbles, simulation ORs or unvalidated mathematical models with debatable assumptions.

4. Real World Data From an Actual Infection Outbreak: Bair Hugger Filter is Effective at Trapping Acinetobacter Baumannii

Acinetobacter baumannii (AB) is rod shaped and has a size of 0.9 - 1.6 micrometers by 1.5 - 2.5 micrometers.
https://catalog.hardydiagnostics.com/cp_prod/Content/hugo/Acinetobacter.htm. During an

actual outbreak of AB in the Netherlands (Bernards et al. 2004), AB was identified in the Bair Hugger filter. The authors specified three interventions that stopped the AB outbreak: 1) cleaning dust where AB had been identified from inside a respirator, 2) cleaning dust from inside a CVVH machine where AB had been identified, and 3) changing the Bair Hugger filter on which AB had been identified. The authors did NOT specify that the interior of the Bair Hugger was cleaned apart from changing its filter, contrary to what could be misconstrued from other summaries of Bernards' paper that I have reviewed.

I have carefully reviewed the Bernards paper. The description of the Bernards study on page 27 of David's report is incorrect and misleading. "After cleaning and filter replacement, the outbreak stopped." (emphasis added) The previous sentence will likely be misconstrued to mean that the Bair Hugger was cleaned. Similarly the Jarvis report (page 12) writes: "After the removal of the dust and replacement of the filters of the Bair Hugger FAW, the first outbreak was stopped". This statement too will be misconstrued as dust being removed from the BH. In fact, the dust was removed from respiratory ventilators and CVVH machines – relevant information that Jarvis does not mention when summarizing the Bernards paper - and that the respirator and CVVH dust were identified as containing AB. The authors only indicate that the Bair Hugger filter was changed and did not mention that the Bair Hugger was cleaned (I do not consider changing the Bair Hugger filter as cleaning the Bair Hugger). On the other hand, the authors specifically mention that accumulated dust inside the ventilator and CVVH machines were cleaned. Given that there is no specific mention of cleaning the Bair Hugger (unlike specific mention of cleaning the ventilator and CVVH machines), we can assume that the Bair Hugger was not cleaned. Given that the outbreak stopped, even though the Bair Hugger interior was not cleaned and only the Bair Hugger filter was changed, this indicates that the interior of the Bair Hugger was not harboring the infectious organism Acinetobacter baumannii that was causing the outbreak. Had the Bair Hugger filter allowed the AB to pass through, then the interior surface of the Bair Hugger downstream of the filter would have harbored AB just like the ventilator and CVVH did. Simply changing the Bair Hugger BH filter would not have stopped the outbreak if the Bair Hugger interior downstream of the filter was harboring AB. The fact that the outbreak was contained after changing the Bair Hugger filter without cleaning the Bair Hugger interior indicates that the existing filter did its job and did not allow AB to pass downstream of the filter. It also means that the AB found on the Bair Hugger filter was on the upstream side of the filter indicating that the AB was trapped by the filter and most likely came from the dust in the electronics and the interior of the respirator and CVVH machine.

5. There is No Indication that Surgical Site Infections are Caused by the Bair Hugger

I disagree with the opinions of Plaintiffs' experts that the Bair Hugger is a significant factor in the increased risk or cause of surgical site infections. Based on the available, credible scientific literature, there is no evidence that the Bair Hugger causes, or is a significant factor in causing surgical site infections (Avidan, Huang, Moretti, Zink). Likewise, there is no evidence that the Bair Hugger increases the risk of surgical site infections. No studies have shown that forced air warming causes infection or should not be used to maintain normothermia in patients. The

theoretical concerns of the plaintiffs and their experts regarding potential disruption of laminar air flow are based on questionable studies[iv], not clinical evidence. There are also other causes of laminar flow disruption such as boom arms or the heads and upper bodies of OR personnel. Further, the efficacy of laminar flow has been questioned. Multiple studies, on the other hand, have shown that forced air warming does not contaminate the surgical site.[v,vi] No studies have demonstrated a causal relationship between the Bair Hugger and a surgical site infection.

There are studies (some using surrogates like bubbles for infectious organisms) and mathematical models that have been produced, but no study has proven a direct cause and effect chain. Causality is not an unattainable or unreasonable bar. Causality can be established as Bernards et al (2004) did in the case of outbreaks of Acinetobacter baumannii. Studies such as Birgand 2015[vii] conclude by suggesting further studies are needed because the evidence is inconclusive.

Also at https://www.cdc.gov/hai/pdfs/stateplans/factsheets/us.pdf, the CDC reports that SSIs have had a significant decrease of 17% in the US. Had the Bair Hugger been the cause of SSIs as alleged by plaintiffs and given its continued widespread use, the expectation is that SSIs should have increased, not decreased.

6. Numerous Potential Causes/Risk Factors of Surgical Site Infections

There are numerous potential causes and risk factors of SSIs. I base my opinion on several grounds, including, but not limited to:

- It is hard to achieve complete sterilization. That may explain why, in spite of best efforts and processes, infections unfortunately still happen. Using the ChloraPrep as it is intended to be used will help to obtain maximum log reduction in CFUs. One log reduction means reducing the amount of bacteria by 90% so that 10% remain, 4 log reduction is a 10^4 (10 to the power of 4) reduction so that 1,000,000 CFUs are reduced to 100 CFUs (99.99% kill) - see https://www.ciriscience.org/a_107-What-is-Log-Reduction. According to the CareFusion web page at http://www.carefusion.co.uk/pdf/Infection_Prevention/Product_Characteristics_Clear.pdf the log reduction of ChloraPrep is >4 and < 6 depending on the organism. This log reduction range means that if there are one million CFUs initially, there is a non-zero probability that there will be one CFU left after PROPER use of ChloraPrep. For example, with a log reduction of 5, there will be ten CFUs left from an initial 1,000,000. The ChloraPrep applicator was likely used for some of the MDL cases; the manufacturer's data indicate that the possibility of one CFU from the patient's skin surviving after skin preparation cannot be excluded. 100% effectiveness or sterility is hard to attain including in skin prepping. Layers of defense against infection such as prophylactic antibiotics can help while predisposing risk factors do not.
- It is unclear whether the proper chlorhexidine applicator scrubbing pattern (to and fro or back and forth) would have been used instead of the more common, but no longer recommended, spiral pattern expanding from the proposed incision site. It is also

unclear if the skin would have been scrubbed for at least 30 seconds with the chlorhexidine gluconate applicator. Log reduction of CFUs will be sub-optimal if the "to and fro" pattern was not used and/or scrubbing was done for less than 30 seconds, among other potential lapses in technique.

- To provide multiple defenses against infection instead of relying on just one, the latest May 2017 CDC Guidelines recommend "8A.1. Advise patients to shower or bathe (full body) with soap (antimicrobial or nonantimicrobial) or an antiseptic agent on at least the night before the operative day. (Category IB-strong recommendation; accepted practice.)" Failure of patients to comply with this recommendation is difficult to monitor without intruding on their privacy. Failure to follow this recommendation leaves a larger number of organisms on the patient's skin that can increase the risk of surgical site infection if the majority of infectious organisms on and around the incision site are not significantly reduced during skin prepping.
- Increased tissue oxygen delivery is recommended for prevention of SSI in the CDC 2017 Guideline.
- Prolonged surgery, unforeseen complications and delays that prolong the time interval from prophylactic antibiotic administration to surgical incision can push the surgery past the recommended time interval for prophylactic antibiotic (Ancef) redosing.
- Pre-existing diabetes is a well-known surgical infection risk.
- Prophylactic antibiotics must be properly adjusted for patient weight.
- There are multiple areas in the OR but outside the sterile area that are not sterile. Multiple sources of bacteria exist in an OR including on the anesthesia machine controls (Loftus et al. 2011, Munoz-Price et al. 2013).[viii,ix]
- Clutter/obstructions above the patient. X-rays are sometimes obtained during surgery. The introduction of an X-ray machine of undetermined/undocumented disinfection in the sterile field is yet another potential source of bacteria. Depending on the radiograph being taken, parts of the X-ray machine may be positioned above the patient or the surgical incision. Boom arms are also used to allow ceiling-hung equipment to be readily positioned where they are needed and swung out of the way when not needed. At a minimum, the boom arms interfere with air flow from the ceiling and in a worst case scenario, the top surfaces of the boom arms will be dusty if not cleaned regularly.

7. Sources of dust, heat and gas outflows in OR

There are multiple sources of gas, beyond a forced air warming blanket, in the operating room including but not limited to those listed below. Many of those gas sources do not have their internal flow passages conveniently accessible for cleaning. In some cases, the air blown into the operating room's ambient environment may also contain infectious organisms or droplets from the patient's respiratory system.

a. Numerous devices in an OR such as physiological monitors, the anesthesia machine, X-ray machines, CVVH machines, OR computers, ceiling-hung display monitors, etc. use electronics that require cooling and blow out the resulting heated air into the OR's

ambient environment. Accumulated dust inside the electronics and interior of the equipment can contain bacteria.

b. The drive gas in some anesthesia machine bellows ventilator exhaust oxygen directly into the OR ambient environment at about head level as demonstrated in the Virtual Anesthesia Machine screen-based simulation. The drive gas outflow is approximately equivalent to the minute ventilation and for an adult can range from 7-10 liters/minute or more. If the bellows that separates circuit gas (gas in contact with the patient's lungs and the internal plumbing in the anesthesia machine) from drive gas (gas squeezing the bellows during inspiration) leaks, then drive gas and circuit gas will mix and circuit gas (containing any infectious organism from the patient's respiratory system) can escape along the outflow path for the drive gas into the OR (Lampotang et al.)[x] at eye level.
c. In the case of an incorrectly set anesthesia machine scavenging system, gases from the breathing circuit exhaust into the room at about knee level without any warning that the scavenging system has failed. Gases spilling out of a malfunctioning or improperly adjusted scavenging system is a source of unsterile gas outflow into the OR. If the patient has respiratory infection, the gas coming out of the breathing circuit has been in contact with the patient's lungs and can carry infectious organisms that are released into the room if the scavenging system fails. Gases exhaled by the patient into the scavenging system are generally warmer that room air because some have been in contact with the patient's lungs and will definitely be warmer if a heater/humidifier is being used in the anesthesia breathing circuit as is done in long duration cases.
d. Anesthesia breathing circuits, including the bellows, are known to leak. Just like with a scavenging system leak, a leak from the anesthesia breathing circuit introduces unsterile gas into the OR.
e. Other sources that spill gas into the OR ambient environment are cuffless endotracheal tubes, ill-fitting cuffed endotracheal tubes, supraglottic devices, or facemasks and open systems such as nasal cannulae, among others.
f. Smoke from surgical cautery is another gas source and has raised concerns about the safety and the potential risk of infection of surgical personnel exposed to it.

There are multiple sources of heat, beyond a forced air warming blanket, in the operating room including but not limited to high intensity surgical lights and endoscopic lights and various electronic equipment. In one study employing computational fluid dynamics and particle-tracking methodology, the total heat emission from these sources, as well as the patient, accounted for more than four times the 500 watts heat dissipation from a forced air warming device.[xi] This study found that with the forced air warmer on or off there was zero percent deposition of contaminant sources on the patient.[xii] The large amount of heat generated by high intensity lights requires a higher flow rate of cooling air to dissipate the heat to keep the equipment cool and functioning properly.

A positive pressure OR can be used for infection control instead of a laminar flow system. Failure of the positive pressure OR system is not a rare occurrence. It is unclear whether the positive pressure system, if present, would have been working properly during the MDL cases. The possibility that the positive pressure system was malfunctioning and might have caused the

infection cannot be ruled out. There is usually no alarm when the positive pressure system fails. OR personnel are often unaware of the tell-tale that allows them to visually check if positive pressure is being maintained inside the OR. Even if OR personnel are aware, it is easy to forget to check the tell-tale or not notice that it is indicating a malfunction because it is usually placed above the door and is therefore usually out of the usual line of sight ("out of sight, out of mind") of OR personnel in the sense that they would have to consciously remember to look up.

Movement/traffic in and out of an OR with opening and closing of doors leading to increased airflow and turbulence can be a factor in increasing particle counts. It is unclear how much traffic occurred during the MDL cases.

8. Latest CDC Guidelines

Further support that there is no evidence of forced air warming causing surgical site infection is provided by a recent JAMA May 2017 paper that describes the Centers for Disease Control and Prevention Guideline for the Prevention of Surgical Site Infection, 2017 (Berrios-Torres et al. 2017)[xiii]. In fact, the 2017 CDC Prevention of SSI Guideline recommends "Maintain perioperative normothermia", an indication that forced air warming devices such as the Bair Hugger are widely used and considered effective in maintaining normothermia. The 2017 CDC guidelines provide new and updated evidence-based recommendations for the prevention of SSI based on a targeted systematic review of the literature conducted in MEDLINE, EMBASE, ClNAHL and the Cochrane Library from 1998 through April 2014. Of note are:

(a) the recommendation to "Maintain perioperative normothermia" which is categorized with the highest level of evidence-based recommendation: 1A. Forced air warming such as provided by the Bair Hugger is a means of maintaining perioperative normothermia; as such, the latest CDC guidelines reaffirm the patient safety contribution of the Bair Hugger in establishing and maintaining normothermia.

(b) the absence of recommendations against forced air warming as a cause of SSI

(c) other factors (but not FAW) that the CDC includes in its guidelines as potential causes of SSIs that should also be considered for the MDL

(d) the guidelines document was published in May 2017 in the Journal of the American Medical Association (JAMA) and represents the latest and most current position of the CDC and infection experts on SSIs.

9. Alternative Designs

Maintaining normothermia (recommended by the latest CDC SSI Prevention Guideline) is an intended function of the Bair Hugger. The ability to establish and maintain normothermia is dependent on the outflow rate of warmed air from the Bair Hugger blanket. A higher outflow

of warm air from the Bair Hugger blanket provides a higher convective heat transfer rate to patients facilitating quicker warming or rewarming. Filters that can trap smaller particles will in general have higher flow resistance and therefore a larger pressure drop across them. This in turn leads to a lower outflow from the Bair Hugger blanket as a result of using a filter that can capture smaller particles. There is therefore a trade-off between filter selection and outflow of warm air (normothermia efficacy) from the Bair Hugger blanket. A HEPA filter (99.97% efficient on particles of 0.3 microns in size) has been mentioned. A HEPA filter will degrade outflow and thus normothermia efficacy compared to the filter selected for the Bair Hugger. Real world results from the field in an actual outbreak of Acinetobacter baumannii suggest that the current filter selected for the Bair Hugger was effective in trapping the infectious organism while having an acceptable pressure drop across the filter that does not significantly degrade the outflow from the blanket, and thus normothermia efficacy.

The David report mentions the Mistral convective forced air warming system that uses HEPA filters: "a HEPA filter would help mitigate some of the risk by preventing the warming unit from collecting and incubating bacteria of its own." First of all, the "risk" is theoretical. The AB outbreak reported by Bernards supports that the Bair Hugger filter does what it was intended to do and may not need to be unnecessarily upgraded to HEPA performance at the potential cost of reduced normothermia efficacy. The AB outbreak and its resolution also strongly suggest with real world evidence that the Bair Hugger filter was effective in "preventing the warming unit from collecting and incubating bacteria of its own." Even a HEPA filter can fail, as Crowder (the corporate representative of the Bair Hugger filter manufacturer, Pentair) asserted during his deposition (p 55): "

Q: ….. would you agree with me that a -- that a HEPA filter is, for all intents and purposes, 100 percent effective at filtering out one-to-three-micron particles?
A. I would say that it is highly efficient, it is very good at removing; I would not use the phrase "100 percent."
Q. Okay.
A. It's not something we would use in relation to our medical filters.

The Warm Touch forced air warming device uses a HEPA filter. Avidan showed that the presence of the HEPA filter in the Warm Touch did not prevent S. Epidermis and Aspergillus Fumigatus from being cultured in the outflow from the Warm Touch that did not flow first through the warming blanket. The fact that the Warm Touch, equipped with a HEPA filter, generated air outflow from which organisms were cultured indicates that a HEPA filter is not a magic bullet. The speculation that adding a HEPA filter will improve the safety of the Bair Hugger is unproven and as discussed may even be detrimental in terms of normothermia efficacy.

The TableGard has been mentioned as an alternative to the Bair Hugger. TableGard is a product to prevent intraoperative development of pressure sores using alternating pressure

redistribution among air cells in a mattress. TableGard uses conductive technology, not convective technology and as such is not an alternative design to the Bair Hugger because it is a different product using a different heat transfer mechanism: conduction instead of convection. Focusing on the flow rate of warmed air out of the blanket and onto the patient, the TableGard cannot be "as effective as the Bair Hugger" – as asserted in the David report on page 40 – because a reduction in flow rate results in a decrease in heat transfer from the blanket to the patient. The flow rate of warmed air out of the blanket and onto the patient in the TableGard is the lowest value it can be at zero, meaning that there is zero convective heat transfer.

VitaHeat has been mentioned as an alternative to the Bair Hugger. VitaHeat is essentially an electric heating blanket that uses conductive technology, not convective technology and as such is not an alternative design to the Bair Hugger because it is a different product using a different heat transfer mechanism: conduction instead of convection.

Silver coating also is not a magic bullet. It did not live up to its promise in dwelling urinary catheters and urine drainage systems. The rate of catheter associated urinary tract infections (CAUTI) did not decrease when silver coating was used. As far as I am aware, the David report did not identify a device with silver coating on internal surfaces. What works in the lab in controlled conditions may not work in the real world. Silver coating, if implemented, may end up adding expense without benefit.

The WarmAir is a convective forced air warming device. It has an airflow of 35 cfm versus 48 cfm for the Bair Hugger (Wagner et al. 2008)[xiv].

The David report states (page 43): "However, the most prudent option is to avoid all air-circulating devices." Any equipment (including electronic ones like computers, monitors, physiological monitors, anesthesia machines, ventilators and CVVH machines) that requires a cooling fan to prevent internal overheating is an air-circulating device. The outflow of air generated by the cooling fan blows heat and dust (and in the outbreak reported by Bernards, Acinetobacter Baumannii) away from the equipment and into the OR. An AB outbreak stopped when previously unsuspected equipment that were likely not appreciated as air circulating devices were found to harbor AB and were subsequently cleaned. Bernards reports that AB was identified in the Bair Hugger filter indicating that the Bair Hugger filter trapped the AB. The recommendation in the David report to "avoid all air-circulating devices" would essentially mean that all equipment with a cooling fan would be removed from the OR, leaving a poorly equipped OR that would present a safety hazard to the patient. Air circulating devices such as HCUs, CVVH and respirators may not have the intake filter that the Bair Hugger has such that any infectious dust can flow unimpeded to the ambient air in the OR.

10. Do Not Blow Air in the OR – Implications

The CDC DRAFT HICPAC Meeting Minutes, November 5-6, 2015 included this sentence that has been quoted in other reports such as David's and Jarvis's: "Nothing that blows air should be in an operating theater, if possible." This sweeping statement taken literally would imply that the

HVAC system, which blows air, should also not be in an OR. A close review of the HICPAC minutes informs us that this sentence was referring to infection resulting from cooling air circulated by a heater cooler unit (HCU). Unlike the Bair Hugger, the HCU uses water; the HICPAC minutes include this text: "In looking inside the machine, it is clear that a reservoir of warm water in a steel container in a chilled operating theater will have condensation that will drip. The insulation layered inside the machine is a non-cleanable foam. The situation is perfect for growing all manner of organisms…. The large cooling fan at the base of the device and louvers on the side of the machine contribute to chaotic dispersal of potentially contaminated air. … There may be concerns associated with the smaller cooling fan that blows air out of the device because it is closer to tables that may hold sterile equipment." There is no water in the Bair Hugger and it is not designed to be used with water unlike the HCU. In fact, when water was accidentally introduced into a Bair Hugger, there was a fire. The clear differences in function and design (including the use of water in the HCU) between the Bair Hugger and the HCU show that there is no basis to assert that the HCU is similar to the Bair Hugger.

Water promotes survival of infectious organisms. The absence of water in the Bair Hugger design (unlike in the HCU) helps mitigate the risk of harboring infectious organisms inside the Bair Hugger. Bacteria also live in water droplets. As Crowder testified (page 52) in terms of removal of bacteria, "My understanding is that bacteria, in order to survive, needs to be in water, needs to be kept wet, so my experience with testing for removal of bacteria in airflows has been to remove droplets of -- of water with bacteria in them." This is consistent with Albrecht 2011[xv] where respiratory droplets are listed among the common forms of "particulate matter suspended in the operating room (OR) air." Droplets of water generally range in diameter from very fine (<60 microns) to ultra coarse (>650 microns) to drops of 4 mm (4,000 microns) and are thus larger than the bacteria they may host which in turn may have an impact on the effective size of bacteria (residing in the droplets) that a filter can trap.

11. Fire in the Bair Hugger (As described in 2017 Moon et al., *Forced air warming device failure resulting in smoke and soot on a surgical patient*).

The fire inside a Bair Hugger unit (at the blower motor downstream of the air intake filter) where soot generated by the fire (combustion) was not trapped by the pores in the Bair Hugger warming blanket has been mentioned in multiple expert reports as an indication that the Bair Hugger blanket does not trap infectious organisms. (Moon et al. 2017)[xvi]

Table 8 (MERV Efficiency Parameters) on page 12 of the Koenigshofer report states that combustion smoke is < 0.3 microns and that most smoke is 0.3 – 1 micron.

Narrowing down the <0.3 micron size range for combustion smoke, if we assume that the soot formed from the Bair Hugger fire is similar in size to Diesel Particulate Matter (DPM) https://www.dieselnet.com/tech/dpm_size.php, then it would be 0.01 to 0.1 micron (micrometer) in size, 90 to 9 TIMES smaller than the smallest dimension (0.9 micron) of, e.g., Acinetobacter Baumannii (AB; rod shaped with a size of 0.9 - 1.6 micrometers by 1.5 - 2.5

micrometers. HEPA filtration – which removes at least 99.97% of 0.3 micron-sized particles (30 times larger than 0.01 micron soot) at the rated flow in accordance with IEST-RP-CC001.3 – would have allowed DPM (0.01 micron soot) to go through it.

From a scientific basis, alleging that the presence of soot on the patient's skin when there was a Bair Hugger fire indicates that the Bair Hugger BLANKET does not trap infectious organisms is weakened by the much smaller size of soot compared to the size and mass (inertia; Crowder deposition) of infectious organisms like AB. To put this in layman's perspective, a ninefold difference (let alone a 90 fold difference) in diameter is larger than even the difference between a basketball (9.4") and a ping pong ball (1.6"). Simply stated as an analogy, that ping pong balls went through does not imply that basketballs will also pass through. http://www.topendsports.com/resources/equipment-ball-size.htm

Furthermore, Avidan demonstrated that the warming blanket was effective in trapping organisms: organisms that were cultured when the outflow of Bair Hugger was sampled without flowing through the blanket were not present when the outflow was sampled after flowing through the Bair Hugger warming blanket.

Conclusion

It is my opinion that the Bair Hugger is a safe and efficacious medical device. It is my opinion that the Bair Hugger was not defectively designed, tested, labeled, or manufactured and that Defendants acted reasonably and within industry standards related to the design, testing, analysis, research, and development of the Bair Hugger Models 775, 750 and 505. Based on available, credible, scientific literature, there is no evidence that the design of the Bair Hugger causes or increases the risk of surgical site infections or is a substantial factor in causing or increasing the risk of SSIs.

Based on available data including actual infection outbreaks where the source of infection was identified (Bernards, HCU), there is no evidence that the Bair Hugger, nor any alleged actions or inactions of Defendants, causes or increases the risk of surgical site infections. The data supporting this conclusion include: (a) the BH filter was effective in trapping AB in an actual outbreak in real world conditions (Bernards), (b) there is no report that I am aware of such as Bernards or the HCU where the Bair Hugger is documented to have caused an infection; (c) HEPA filtration did not prevent Avidan from culturing organisms from a Warm Touch; absence of HEPA filtration does not necessarily make a design less safe, (d) the BH blanket acts as an additional filter as reported by Avidan and (e) some studies that have raised concerns about the BH have used surrogates such as bubbles or mathematical models; the validity of these surrogates or models depends on the assumptions and simplifications made.

The opinions in this report are given to a reasonable degree of engineering and scientific certainty. They are based upon my education, training, experience, as well as the above list of materials reviewed.

This report is not meant to be an exhaustive recitation of all of my opinions. I reserve the right to amend and supplement the opinions expressed in this report. I also reserve the right to respond to and rebut all information provided in discovery, which I understand is ongoing, specifically including any opinions offered by Plaintiffs' experts at their depositions or at trial.

Samsun Lampotang, Ph.D.

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